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Date: 18 September 2004

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FAX TO: Mr. Arlen Soderquist FAX No. 001 703 872 93 06

FROM: Mr Dirk Nehring (total 23 pages)

Application Number: 10/022,406 Applicants: Nehring ET AL

Art Unit: 1743

Dear Mr Soderquist

Thank you for your correspondence regarding the above US patent application and the reasons why it has initially been rejected.

Regarding the disposition of the claims; Claims 1 to 19 have initially been rejected. We have revised these as you correctly pointed out that as originally written, in the most part it seems obvious to one of ordinary skill in the art of the time of the invention, given the previous US Patents cited by you, that the invention could have been arrived at. We have addressed each of these patents as follows;

In U.S. Pat. No. 5,235,819 an apparatus for storing and distributing materials is described. The apparatus maintains products at an intended temperature during transporation and storage at an ambient temperature deviating from the intended temperature. The invention features a container that holds the products and whose walls render heat transfer difficult. The container includes a main container body with a bottom and a side section that together define one or more integrated compartments suitable for storing a solidifiable substance.

The invention does not consist of modular identical halves or frame structures that may be stacked on top of each other to create a flexible, modular system enabling variable inner volumes to suit different product sizes, thus maximising the inner volume for the amount of product being stored whilst also being completely surrounded by the temperature-regulating fluid. The fact that this transport apparatus is not modular makes it impossible to transport variable volumes of products such as medications, blood and organs, which are the intended products to be transported in the system invented by Nehring and Bienert.

An insulated modular cooler comprising in one embodiment a plurality of tubular housing sections and a plurality of tubular hollow-walled insert housing containing a refrigerant in the hollow walls of the insert housings was invented by Basso (4,517,815). The tubular housing sections can be secured end to end to form an elongated tubular hosing. However the resultant system has to have an end cap to secure the product being transported inside, Whit is the product of the insert housing in the compartment of the tubular housing. There is no cooling fluid within this enducation where the product of the tubular housing. There is no cooling fluid within this enducation where the secure of the tubular housing.

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means that the cooling fluid does not surround the entire inner compartment. Furthermore, another bottom cap is required to close the system. The temperature stability of the product to be transported is less therefore predictable because the cooling fluid does not surround the inner compartment completely. The invention does not consist of modular identical halves that may be stacked on top of each other, which require neither an end or bottom cap as is the case in this Nehring and Bienert invention, whereby the product being transported is totally surrounded by temperature regulating fluid.

A combination dental material mixing slab holder and cooler which includes a base plate having a pair of spaced, upwardly projecting ribs and a central well was invented by Drake (3,858,410). This patent teaches that the heat sink means it is a stable liquid or solid material, having a relatively high latent or heat capacity. However, no modular dispositions are explained and the cooling liquid or solid material does not surround the inner compartment completely. The temperature profile through the cross sections is inhomogeneous due to the different conductivity of the lid and the container itself.

Various phase change formulations usable in thermal packaging systems using a single phase change material part in liquid and part in solid form to confine the temperature of the product within a predetermined range was described by Malach (6,482,332). The temperature ranges are determined by selection of the phase change material. Blends such as butandiol, selected amounts of distilled water and nucleating agents can be formulated to achieve phase changes from $+40^{\circ}$ to -30° C. However Malach does not describe a modular system or a double walled apparatus that surrounded the inner compartment completely by phase change material. Furthermore the construction of the described container requires an end cap and a bottom cap for closure.

Sheehan invented a portable cooler for use in transporting medicines including an insulative housing containing a coolant (4,322,954). One compartment is made for a coolant and the other for the product. A heat tube connects both compartments. The device includes a carrying strap and latches. The device is not constructed like a modular expandable system and the cooling liquid or material does not directly or completely surround the product to be transported.

MacDonald teaches in patent (5,058,397) a cryogenic storage container for biological specimens that include a cooling gel or medium to keep the specimens at a low temperature. The storage box includes a rectangular housing having a chamber filled with a coolant gel, and a plurality of spaced, tube supporting wells opening at their upper ends. A cover, which is connected to the housing, contains a sealed envelope containing coolant gel. The device includes hinges and latches, but does not consist of a modular system that surrounds the inner volume completely.

Schea (5,181,394) disclosed a shipping unit for containers of liquid compositions, such as solutions of biologically active proteins. A phase change material such as carboxymethylcellulose gel is disposed in the enclosed space between sidewalls and maintains the temperature of the inner containers. A freeze indicator provides an irreversible visual signal upon reaching a temperature intermediate the nucleation temperature of the liquid composition and the freezing temperature of the phase change material. Thus thermocouple devices of varying kinds and simple devices such as described in U.S Pat. Mo. 4,191,125 are quite suitable as the freeze indicators. However, the device of Schea can not be used as a modular system to increase the inner volume and it is not constructed to surround an inner compartment by phase change material to avoid heat bridges.

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Since it would be obvious to one of ordinary skill in the art that complete surrounding of the inner compartment enhances the temperature stability of the inside product it is not obvious for one of ordinary skills to combine both features of modularity and the complete surrounding of phase change material and also construct this by avoiding a double walled system without an end cap or bottom cap.

Regarding the application papers the drawings have also been revised to show in more clarity the parts of the invention and their pertinance to it. We have paid particular note to your comment ("It is not clear what structure consitutes a clip"). We have revised this to rename the "clip" as "notches and indentations" as they are notches and indentations moulded into the system (Fig 1 shown as 11 and 2). Furthermore the structure names as "ring" (figure 3; 20) was renamed as "double wall frame".

The certified copies of the prior European Patent 0124070.2 have been requested from the European Patent offices and will be sent to you as soon as we receive them.

We trust that our amendments explain the points you made in full. We are aware that your time is limited, so should you require any further assistance whilst processing our US Patent application, you may contact us by email at info@deltaT.de and we will answer you promptly or call you if you prefer.

Kind regards

Dirk Nehring